

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC.,
a New Jersey corporation; and
QUEEN'S UNIVERSITY AT
KINGSTON, a Canadian academic
organization,

Plaintiffs,

v.

NEW ENGLAND COMPOUNDING
PHARMACY, INC., a Massachusetts
corporation,

Defendant.

MAGISTRATE JUDGE RBC

04 12703 NMG
Civil Action No.

[JURY TRIAL DEMANDED]

RECEIPT # 11039
AMOUNT \$ 150.00
SUMMONS ISSUED 1
LOCAL RULE 4.1 -
WAIVER FORM -
MCF ISSUED -
BY DPTY. CLK. MP
DATE 12/27/04

COMPLAINT

Plaintiffs, DUSA Pharmaceuticals, Inc. ("DUSA") and Queen's University at Kingston ("Queen's University"), through their counsel, hereby allege the following for their Complaint against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"):

JURISDICTION AND PARTIES

1. This is a civil action for inducing patent infringement of United States Patent Nos. 6,710,066 ("the '066 patent"); and 5,955,490 ("the '490 patent"). This Court has jurisdiction under 28 U.S.C. § 1331 and § 1338(a). Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and §1400(b).

2. Plaintiff DUSA is a corporation organized under the laws of the State of New Jersey having its principal place of business at 25 Upton Drive, Wilmington, MA 01887.

3. Plaintiff Queen's University is a public university registered in the province of Ontario and located in Kingston, Ontario, Canada.

4. On information and belief, Defendant NECC is a for profit corporation incorporated under the laws of the Commonwealth of Massachusetts, having a principal place of business at 697 Waverly Street, Framingham, MA 01702.

5. Defendant NECC conducts business, has induced others to commit acts of infringement and resides in this Commonwealth and Judicial District, and a substantial part of the events giving rise to the claim occurred in this Judicial District.

COUNT I

CLAIM FOR INDUCEMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,710,066

6. The '066 patent, entitled "Photochemotherapeutic Method Using 5-Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins," was duly and lawfully granted on March 23, 2004, by the United States Patent and Trademark Office. The '066 patent is owned by Plaintiff Queen's University and is exclusively licensed to Plaintiff DUSA.

7. Plaintiff DUSA, under its license from Plaintiff Queen's University, manufactures, offers for sale, and sells pharmaceutical compositions containing aminolevulinic acid under the trademark "Levulan®" for use in the treatment of actinic keratosis, as covered by the '066 patent.

8. Upon information and belief, Defendant NECC sells aminolevulinic acid solution, advertises the use of NECC's aminolevulinic acid solution for treatment of actinic keratosis, instructs others to use NECC's aminolevulinic acid solution for actinic keratosis treatment and thereby actively induces others to treat actinic keratosis with NECC's aminolevulinic acid solution by infringing the '066 patent under 35 U.S.C. § 271(b).

9. Upon information and belief, Defendant NECC is sending unsolicited facsimiles to physicians advertising aminolevulinic acid solution for the treatment of actinic keratosis. Copies of such facsimiles are attached as Exhibits A and B and are hereby incorporated by reference.

10. Defendant NECC's activities in inducing infringement of the '066 patent are knowing, willful and wanton under 35 U.S.C. § 284 and make this an exceptional case under 35 U.S.C. § 285.

COUNT II

CLAIM FOR INDUCEMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 5,955,490

11. The '490 patent, entitled "Photochemotherapeutic Method Using 5-Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins," was duly and lawfully granted on September 21, 1999, by the United States Patent and Trademark Office. The '490 patent is owned by Plaintiff Queen's University and is exclusively licensed to Plaintiff DUSA.

12. Upon information and belief, Defendant NECC sells aminolevulinic acid solution, advertises the use of NECC's aminolevulinic acid solution for treatment of acne using light therapy, instructs others to use NECC's aminolevulinic acid solution for acne treatment and thereby actively induces others to treat acne with NECC's aminolevulinic acid solution by infringing the '490 patent under 35 U.S.C. § 271(b).

13. Upon information and belief, Defendant NECC is sending unsolicited facsimiles to physicians advertising aminolevulinic acid solution for the treatment of acne. Copies of such facsimiles are attached as Exhibits A and B and are hereby incorporated by reference.

14. Defendant NECC's activities in inducing infringement of the '490 patent are knowing, willful and wanton under 35 U.S.C. § 284 and make this an exceptional case under 35 U.S.C. § 285.

WHEREFORE, Plaintiffs pray that:

(a) Defendant NECC be preliminarily and permanently enjoined from actively inducing others to infringe United States Patent No. 6,710,066;

(b) Defendant NECC be preliminarily and permanently enjoined from actively inducing others to infringe United States Patent No. 5,955,490;

(c) Defendant NECC be ordered to pay compensatory damages as a result of its actively inducing infringement of United States Patent No. 6,710,066, including all damages suffered by Plaintiffs as a result of the infringement, increased by three times for willful behavior;

(d) Defendant NECC be ordered to pay compensatory damages as a result of its actively inducing infringement of United States Patent No. 5,955,490, including all damages suffered by Plaintiffs as a result of the infringement, increased by three times for willful behavior;

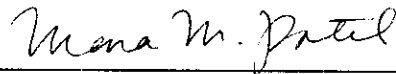
(e) Plaintiffs be awarded their costs of this action including reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

(f) Plaintiffs be awarded such other further relief as the Court shall deem appropriate.

Respectfully submitted this 27th day of December 2004.

DUSA PHARMACEUTICALS, INC. and
QUEEN'S UNIVERSITY AT KINGSTON

By their attorneys,



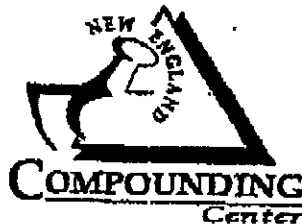
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Nov-11-04 02:18pm From: THE CENTER FOR COSMETIC CARE

+9529298669

T-090 P.002/004 F-836



New England Compounding Center

Customized Pharmacy Services

697 Waverly Street, Framingham, MA 01702

Tel: 800.994.6322 or 508.820.0606

Fax: 888.820.0583 or 508.820.1616

www.neccrx.com mail@neccrx.com

Are you treating acne patients with Blue Light Therapy?

We may be able to help!

New England Compounding Center can provide you with, on a prescription basis, 20% aminolevulinic acid solution in a convenient 2ml screw top vial.

Advantages:

- Easy to apply
- Great for larger surface areas
- Reconstitute on site

New England Compounding Center has earned a national reputation as a provider of compounded pharmaceuticals and excellent service to patients and prescribers.

Please call today to discuss your needs 800-994-6322.

We would appreciate the opportunity to serve you and your patients.

Nov-11-04 02:18pm From:THE CENTER FOR COSMETIC CARE

+9528299559

T-090 P.003/004 F-035

Directions for Reconstitution

Aminolevulinic Acid 20% (ALA)

- 1) Aminolevulinic Acid (ALA) is stored in the refrigerator
- 2) When ready to use, open the silver packet which contains 2 vials:
 - a. ALA (Solvent) Solution, (1.5 ml)
 - b. ALA 20% 354mg Powder
- 3) Open the vial labeled "ALA (Solvent) Solution" and pour the contents into the vial labeled "ALA 20% 354mg Powder", creating a 2 ml volume of a 20% ALA Solution.
- 4) Screw cap on the vial tightly and shake well; may take 4 to 5 minutes for the powder to dissolve.
- 5) The ALA solution expires in 2 hours once reconstituted.
- 6) The ALA solution is for external use and can be applied with the enclosed brush or any other suitable swab.

Nov-11-04 02:18pm From: THE CENTER FOR COSMETIC CARE

+9528289669

T-000 P.004/004 F-836

Patient Advisory Leaflet

Aminolevulinic Acid 20% (ALA)

Aminolevulinic Acid 20% (ALA) is a naturally occurring photosensitizing compound which has been approved by the FDA to treat pre-cancerous skin lesions called actinic keratosis. ALA is applied to the skin and subsequently "activated" by specific wavelengths of light. This process of activating ALA with light is termed Photodynamic Therapy. The purpose of activating the ALA is to improve the appearance and reduce acne rosacea, acne vulgaris, sebaceous hyperplasia, decrease oiliness of the skin and improve texture and smoothness by minimizing pore size. Any pre-cancerous lesions are also simultaneously treated. The improvement of these skin conditions (other than actinic keratosis) is considered an "off-label" use of ALA.

ALA is normally applied to the skin for 30 – 90 minutes. Subsequently, the area will be treated with a specific wavelength of light to activate the ALA. Following treatment, the ALA is washed from the skin. The patient should avoid direct sunlight for 24 hours following the treatment due to photosensitivity.

Anticipated side effects of ALA treatment include discomfort, burning, swelling, redness and possible skin peeling, especially in any areas of sun damaged skin and pre-cancers of the skin, as well as lightening or darkening of skin tone and spots, and possible hair removal. The peeling may last many days and the redness for several weeks if you have an exuberant response to treatment.

B



New England Compounding Center
Customized Pharmacy Services
697 Waverly Street Framingham, MA 01702
(508) 820-0606, (800) 994 - NECC
Fax (508) 820-1616 or (888) 820 0583
www.neccrx.com

Dr. Mark Nestor

Fax# 305-933-6720

From: Pat Hill

Phone: 508-820-0606 ext. 609

Date: 10/29/2004

3 PAGES

Thank you for your interest in our prescription compounding services.

Our **20 % Aminolevulinic Acid (ALA)** solution is dispensed in a 1ml and 2 ml volume.

Price per vial is \$xx.00 @ quantity 6 vials @ 2 ml volume

Price per vial is \$xx.00 @ quantity 6 vials @ 1 ml volume

A number of physicians have come to our pharmacy looking for a better way to apply this topical medication to larger treatment areas.

It has a 6 month beyond use date (unmixed)

We supply a convenient applicator brush with each vial.

Medication is shipped cold.

To order:

- Please fax in a script from the doctor with his DEA# and address.
- Fax to # 888-820-0583
- List 1 patient name for every 3 vials. (i.e. 6 vials = 2 patient names)
- Include your Credit Card information.

Pat Hill

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- 6) The ALA solution is for external use and can be applied with the enclosed brush or any other suitable swab.

CIVIL COVER SHEET

The US-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required by the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I(a) PLAINTIFFS

DUSA Pharmaceuticals, Inc. and Queen's University at Kingston

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Middlesex
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

New England Compounding Pharmacy, Inc.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Mona M. Patel, Esq., Holland & Knight LLP, 10 St. James Avenue,
Boston, MA 02116 (617) 523-2700
Maryellen Feehery, Esq., Reed Smith LLP, 2500 One Liberty Place,
Philadelphia, PA 19103 (215) 851-8100

ATTORNEYS (IF KNOWN)

04 12703 NMG

II. BASIS OF JURISDICTION

(PLACE AN X IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff Plaintiff
☐ 2 U.S. Government Defendant
☒ 3 Federal Question (U.S. GOVERNMENT NOT A PARTY)
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(FOR DIVERSITY CASES ONLY)

(PLACE AN X IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

	PTF	DEF		PTF	DEF
Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

IV. NATURE OF SUIT

(PLACE AN X IN ONE BOX ONLY)

CONTRACT	PERSONAL INJURY	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability	<input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 362 Personal Injury--Med Malpractice <input type="checkbox"/> 365 Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability <input type="checkbox"/> 390 Other Personal Property	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademarks	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Other	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID title XVI <input type="checkbox"/> 865 RSI (405(g)) <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS - Third party 26 USC 7609	

V. ORIGIN

(PLACE AN X IN ONE BOX ONLY)

- ☒ 1 Original Proceeding
☐ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Reopened
☐ 5 Transferred from another district (specify)
☐ 6 Multidistrict Litigation
☐ 7 Appeal to District Judge from Magistrate Judgement

VI. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

35 U.S.C. § 271(6); 35 U.S.C. §§ 284, 285. Defendant induced the infringement of patents owned by and/or licensed to the plaintiffs.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION

☐ UNDER F.R.C.P. 23

DEMAND \$ Injunctive relief

compensatory damages

Check YES only if demanded in complaint:

JURY DEMAND: ☒ YES ☐

VIII. RELATED CASE(S) IF ANY

(See instructions): N/A

Judge _____

Docket Number _____

Date 12/27/04

SIGNATURE OF ATTORNEY OF RECORD

Mona M. Patel

For OFFICE USE ONLY

RECEIPT#

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. Title of case (name of first party on each side only) DUSA Pharmaceuticals, Inc. v. New England Compounding Pharmacy, Inc.
2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).
- ☐ I. 160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.
- ☒ II. 195, 368, 400, 440, 441-444, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950. *Also complete AO 120 or AO 121 for patent, trademark or copyright cases
- ☐ III. 110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.
- ☐ IV. 220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.
- ☐ V. 150, 152, 153.
3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.
4. Has a prior action between the same parties and based on the same claim ever been filed in this court?
YES ☐ NO ☒
5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)
YES ☐ NO ☒
- If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
YES ☐ NO ☐
6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?
YES ☐ NO ☒
7. Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).
YES ☐ NO ☒
- A. If yes, in which division do all of the non-governmental parties reside?
Eastern Division ☒ Central Division ☐ Western Division ☐
- B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?
Eastern Division ☐ Central Division ☐ Western Division ☐
8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)
YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Mona M. PatelADDRESS Holland & Knight LLP, 10 St. James Avenue, Boston, MA 02116TELEPHONE NO. (617) 523-2700